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**CALIFORNIA DEPARTMENT OF HEALTH SERVICES
SMALLPOX VACCINATION PROGRAM**

NATIONAL AND CALIFORNIA VACCINATION CONTRAINDICATIONS POLICY

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GENERAL GUIDANCE

The primary concern of the California Department of Health Services (CDHS) is to conduct the smallpox vaccination program with the highest degree of safety. The following general principles of screening should apply.

1. Borderline or unclear circumstances should be interpreted conservatively as a contraindication to vaccination. In any case where doubt exists, do not vaccinate.
2. Any vaccinator may withhold vaccination if he or she is uncomfortable with the ability of the proposed vaccine recipient to properly care for the vaccination site or protect third parties from inadvertent infection. The vaccinator is not obliged to vaccinate anyone who demands vaccination despite contraindications in themselves or a family member.

Local Health Departments who are participating in the CDHS voluntary smallpox preparedness vaccination program will follow current Advisory Committee on Immunization Practice (ACIP) and Centers for Disease Control and Prevention (CDC) contraindications for smallpox vaccination.

ACIP/CDC CONTRAINDICATIONS FOR VACCINEES AND HOUSEHOLD CONTACTS

Smallpox vaccination in the pre-outbreak setting is contraindicated for persons who have the following conditions or have a household contact with the following conditions. For the purpose of screening for contraindications, "household contacts" should be considered to include persons with prolonged intimate contact with the potential vaccinee, including the potential for direct contact with the vaccination site, e.g., sexual contacts.

- Smallpox vaccine should not be administered to persons with a history of eczema or atopic dermatitis, irrespective of disease severity or activity or a household contact with these conditions. This applies even if no rash is currently present. The terms eczema and atopic dermatitis often are used interchangeably. The criteria to suspecting these conditions are a history of an itchy red rash that comes and goes. Sometimes this recurrence is in response to a known stimulus, but often the rash can reappear for no apparent reason. A defect in cell-mediated immunity underlies these conditions, and this defect is present even when there is no rash.
- Persons with other active acute, chronic, or exfoliative conditions that disrupt the epidermis or cause fissuring of the skin (e.g., burns, impetigo, varicella zoster, herpes, severe acne, psoriasis, and other conditions resulting in open skin lesions) are at higher risk for clinically significant inadvertent inoculation and should not be vaccinated until the condition resolves. A history of herpes simplex or shingles in the past is not a contraindication to vaccination, as long as no lesions or other contraindications are present. Smallpox vaccine should not be administered to persons whose household contacts have any of these active skin conditions. Darier disease (keratosis follicularis) is a contraindication in a potential vaccinee and a contraindication if a household contact has active disease.

- Persons who are immunocompromised as a result of human immunodeficiency virus or acquired immunodeficiency syndrome (HIV, AIDS), leukemia, lymphoma, generalized malignancy, solid organ transplantation, cellular or humoral immunodeficiencies, or therapy with alkylating agents, antimetabolites, radiation, or high-dose corticosteroids. Autoimmune disorders, including systemic lupus erythematosus that is moderate to severe, or treated with immunosuppressants may also be associated with immunodeficiency. Cancer that has been cured or is in remission is not necessarily a contraindication as long as the person in question is not on immunosuppressive medication and has no other contraindications. A household contact with any of these conditions is also a contraindication.
- Any person on chronic maintenance steroids should be screened carefully. People on inhaled steroids for asthma are not contraindicated. However, people on a short burst of steroids for an acute condition should probably forgo vaccination until the illness has resolved, less because of the steroids than because of the acute illness.
- Pregnant women or women who desire to become pregnant in the 28 days after vaccination, or persons with such household contacts, should not receive smallpox vaccine. Sexually active female vaccinees of childbearing age should use a reliable form of birth control until the vaccination scab separates.

ACIP/CDC CONTRAINDICATIONS THAT APPLY ONLY TO VACCINATION CANDIDATES – NOT CLOSE CONTACTS

- Breastfeeding women should not receive the vaccination, because it is not known whether the virus is excreted in breast milk.
- Any moderate to severe acute illness in an otherwise healthy individual is a contraindication to vaccination until the acute illness has resolved.
- Asthma, per se, is not a contraindication to vaccination provided no other contraindication is present. Some patients with asthma have associated atopy, which is the reason this condition is solicited in the screening document.
- Severe, life-threatening allergy to any vaccine component, such as polymixin B, streptomycin, chlortetracycline, or neomycin is a contraindication to vaccination. However, a household contact with these allergies is not a contraindication.
- Inflammatory conditions of the eye requiring the use of ophthalmic topical steroids. Vaccination can be done when the inflammation has resolved and steroids discontinued.
- People under 18 years of age should not receive vaccine in this non-emergency program. CDC recommends 65 years of age as an upper age limit for this program.
- Have been diagnosed by a doctor as having a heart condition with or without symptoms, including conditions such as previous myocardial infarction (heart attack), angina (chest pain caused by lack of blood flow to the heart), congestive heart failure, cardiomyopathy (heart muscle becomes inflamed and doesn't work as well as it should), stroke or transient ischemic attack (a "mini-stroke" that produces stroke-like symptoms but not lasting damage), chest pain or shortness of breath with activity (such as walking up stairs), or other heart conditions being treated by a doctor. (While this may be a temporary exclusion, these people should not get the vaccine at this time.)
- Have 3 or more of the following risk factors: high blood pressure diagnosed by a doctor; high blood cholesterol diagnosed by a doctor; diabetes or high blood sugar diagnosed by a doctor; a first degree relative (for example, mother, father, brother, sister) who had a heart condition before the age of 50; and, you smoke cigarettes now. (While this may be a temporary exclusion, these people should not get the vaccine at this time.)

CALIFORNIA POLICY FOR PERSON LIVING WITH A CHILD UNDER 12 MONTHS OF AGE

The CDHS policy is to defer vaccination of candidates who have an infant less than 1 year of age in the household until the child is one year of age.

ACIP and CDC do not consider the presence of an adolescent or child (including an infant) in the vaccine recipient's household to be a contraindication to vaccination. Data suggest that the risk of serious complications of transmission from an adult to a child is extremely small and this transmission is preventable using good hygiene and vaccination site care. Nonetheless, ACIP recognizes that some programs may defer vaccination of house hold contacts of infants less than 1 year of age because there is data suggesting a higher risk of adverse events among primary vaccine recipients in this age group, compared with that among older children, especially encephalitis. In addition, breast-feeding an infant is a contraindication. Because of these concerns, the CDHS policy is to defer vaccination of candidates who have an infant less than one year of age.

POLICY UPDATES

This list of contraindications will change over time, as we gain experience with the vaccination both nationally and locally. Additional experience, new research, and recommendations by professional societies based on review of past experience may also result in further clarification of the contraindications or added ones.

In the event of an actual smallpox outbreak, this list would change considerably. Furthermore, for individuals directly exposed to smallpox, there are no contraindications to vaccination.